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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,454	12/08/2003	Arne Agerlin Olsen	5676.210-US	3283

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EXAMINER	
LIU, SUE XU	

ART UNIT	PAPER NUMBER
1639	

MAIL DATE	DELIVERY MODE
07/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/730,454	OLSEN ET AL.	
	Examiner	Art Unit	
	Sue Liu	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-34* is/are pending in the application.

4a) Of the above claim(s) *29-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice of non-compliant Amdt.*

DETAILED ACTION

Claim Status

1. Claims 1-21 have been cancelled.

Claims 22-34 are currently pending.

Claims 29-34 have been withdrawn.

Claims 22-28 are being examined in this application.

Non-Compliant Claim Amendment

2. Applicants have amended the claims, however, the claim amendment is not compliant. Applicants are respectively directed to the attached "Notice of Non-compliant Amendment" for additional information.

Election/Restrictions

3. Applicant's election with traverse of Group I (Claims 22-28 with SEQ ID NO. 88) in the reply filed on 9/5/06 is as previously acknowledged.

4. This application contains claims 29-34 and SEQ ID Nos (64 and 89-99) drawn to inventions nonelected with traverse in the reply filed on 9/5/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

5. Applicant's election without traverse of the following species:

A. the immunogenicity of the protein variant is below 75% of the immunogenicity of the parent protein;

B. the host cell is a bacterium;

C. the protein is an enzyme.

in the reply filed on 9/5/2006 is as previously acknowledged.

Priority

6. This application appears to be a CONTINUATION of U.S. Patent Application Nos. 09/417,608 (filed 10/13/1999), which is now a US PATENT, 6,686,164 (2/3/2004). The '164 patent claims benefit of the following provisionals:

60/157,429 (10/04/1999)

60/114,386 (12/08/1998)

60/107,165 (11/05/1998).

7. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32

USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application Nos. 60/114,386 and 60/107,165, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Both of the provisional applications ('386 and '165) do not disclose the specific "epitope pattern" of RYPR (SEQ ID NO 88) and RYPK, as recited in the instant Claim 27.

Thus, the priority date for the subject matter claimed in the instant Claim 27 is 10/04/1999.

8. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/417,608, filed on 10/13/1999.

Specification

Sequence Rule Compliance

9. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825 for the reason(s) below:

The disclosure is objected to because of the following informalities: The instant disclosure recites lists of sequences in the claims (Claim 27) and drawings, which are not identified by their corresponding SEQ ID Nos in the "BRIEF DESCRIPTION OF THE

FIGURES AND TABLES" of the instant specification. Applicants are requested to amend the instant specification and claims accordingly.

Appropriate correction is required.

In order to be fully responsive to the instant Office action, Applicants are requested to fully comply with the Sequence Rule as indicated above.

10. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections Maintained

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description Rejection

12. Claims 22-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The previous rejection is maintained for the reasons of record as set forth in the

previous Office action.

Discussion and Answer to Argument

13. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants state "The specification contains an extensive disclosure of wild-type proteins from which the protein variants of the present invention are derived", and "the skilled artisan would be led to make other protein variants". (Reply, p. 4).

Applicants have made the above assertion without providing any supporting evidence. Specifically, applicants did not point out the specific recitation within the instant disclosure that provide support to show possession of the entire claimed genus of "protein variant having reduced immunogenicity".

As discussed in the previous Office action (mailed 11/16/06; pp. 7-10), the state of the art for generating various "protein variants with reduced immunogenicity" is highly unpredictable, as evidenced by the previously cited references.

(see MPEP 2163 II)

Scope of Enablement Rejection

14. Claims 22-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making and using protein variants based on Savinase listed on pp. 54-58 of the instant specification, does not reasonably provide enablement for making and using for

protein variants that are based on other parent proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The previous rejection is maintained for the reasons of record as set forth in the previous Office action.

Discussion and Answer to Argument

15. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants argue it would not require "undue experimentation" to make and use the claimed invention in its full scope. Applicants generally state "the specification contains an extensive disclosure of wild-type proteins form which the protein variants are derived," and "the skilled artisan would be led to make other protein variants". (Reply, p. 5).

Applicants have made the above assertion without providing any supporting evidence. Specifically, applicants did not point out the specific recitation within the instant disclosure that provide support to show possession of the entire claimed genus of "protein variant having reduced immunogenicity".

As discussed in the previous Office action (mailed 11/16/06; pp. 7-10), the state of the art for generating various "protein variants with reduced immunogenicity" is highly unpredictable, as evidenced by the previously cited references.

Applicants also discussed "In re Angstadt" in length.

However, the fact pattern of the instant application is different from the fact pattern of In re Angstadt. Unlike In re Angstadt, the instant claims are drawn to a genus of biological molecule, "protein variants having reduced immunogenicity". (See *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, *>1566-67<, 43 USPQ2d 1398, *>1404-05< (Fed. Cir. 1997; "In addition, Angstadt is an enablement case and *Utter* involves machinery of limited scope bearing no relation to the complex biochemical claims before us.")

"As illustrated in extensive precedent on the question of how much experimentation is "undue", each case must be determined on its own facts." (see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988)).

As discussed in the previous Office action, the term "protein variants" encompasses almost any polypeptide or peptides with any structure and amino acid sequences. The making and using of highly complex biological macromolecules (such as proteins) are vastly different from small chemical catalyst (such as the one discussed in In re Angstadt).

Applicants have not specifically disputed the previously cited references to indicate the predictability of the art for making "protein variants having reduced immunogenicity". (see previous Office action, mailed 11/16/06; pp. 13+). Applicants have not provided evidence to show that the experimentation required to make and use the instantly claimed invention would NOT be undue.

The case laws have provided guidance for claims drawn to complex biological macromolecules. For example:

Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1205, 18 USPQ2d 1016, 1020 (Fed. Cir. 1991):

"what is necessary is that he provide a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of his claims. For DNA sequences, that means disclosing how to make and use enough sequences to justify grant of the claims sought. Amgen has not done that here. In addition, it is not necessary that a court review all the *Wands* factors to find a disclosure enabling. They are illustrative, not mandatory. What is relevant depends on the facts, and the facts here are that Amgen has not enabled preparation of DNA sequences sufficient to support its all-encompassing claims."

In the instant case, the instant specification has not show "enough" sequences to justify the entire claimed scope of invention.

Second paragraph of 35 U.S.C. 112

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 24, 25 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The previous rejection over claims 24, 25 and 27 is maintained for the reasons of record as set forth in the previous Office action. The rejection over claims 22, 23, 26, and 28 is withdrawn due to applicant's amendment to the claims.

A.) Claim 24 recites the limitation "the epitope pattern" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 23 from with claim 24 depends on recite "epitope patterns" in plural. It is not clear to which epitope the term in Claim 24 is referring.

B.) Claim 25 recites the limitation "the epitope" in line 25. There is insufficient antecedent basis for this limitation in the claim. The instant specification discloses that the terms "epitope" and "epitope area" are referring to different entities. For example, in Figure 1 of the

instant disclosure, both the epitope and the epitope areas within the epitope are shown (p. 5, lines 5+).

C.) Claim 27 recites the sequence "RYPR/K" followed by SEQ ID No: 88, which is unclear. The SEQ ID No. 88 as recited in the submitted Sequence Listing and in the instant specification (p. 50, Table 2) is referring to the sequence "RYPR", and does not refer to the sequence "RYPK". It is not clear as to which epitope sequence the instant Claim 27 is limited.

Discussion and Answer to Argument

18. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants state the claim amendment overcomes the previous rejection. However, applicant's amendment to the claims does not address all previous rejections as set forth above and previously.

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 22-26 and 28 are rejected under **35 U.S.C. 102(b)** as being anticipated by

Lovborg et al (WO 92/10755; 6/25/1992; cited in IDS, filed 12/8/03). The previous rejection is maintained for the reasons of record as set forth in the previous Office action.

Discussion and Answer to Argument

21. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants generally argue "Lovborg do not disclose the protein variants of the present invention". (Reply, p. 7, bottom).

Applicants made the above assertion without providing any rationale for why the "Lovborg" reference does not teach the instantly claimed "protein variant". Applicants are respectively directed to the previous Office action (mailed 11/16/06; pp. 17-18) for detailed discussion of how the reference's teaching anticipates the instant claimed invention.

Double Patenting

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. Claims 22-26 and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-24, and 26-29 of copending Application No. 09/957806 (20050181446; 9/21/01). The previous rejection is maintained for the reasons of record as set forth in the previous Office action.

Discussion and Answer to Argument

24. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants state "applicants will file a terminal disclaimer upon an indication of allowable subject matter". (Reply, p. 8).

However, the instant claims are not allowable. Thus, the ODP rejection is maintained for the reasons of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SL
Art Unit 1639
7/18/07

/Jon D. Epperson/
Primary Examiner, AU 1639

Notice of Non-Compliant Amendment (37 CFR 1.121)	Application No.	Applicant(s)	
	10/730,454	OLSEN ET AL.	
	Examiner	Art Unit	
	Sue Liu	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The amendment document filed on *07 May 2007* is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
  - ☐ A. Amended paragraph(s) do not include markings.
  - ☐ B. New paragraph(s) should not be underlined.
  - ☐ C. Other _____.
- ☐ 2. Abstract:
  - ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
  - ☐ B. Other _____.
- ☐ 3. Amendments to the drawings:
  - ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
  - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
  - ☐ C. Other _____.
- ☒ 4. Amendments to the claims:
  - ☐ A. A complete listing of all of the claims is not present.
  - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
  - ☒ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
  - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
  - ☒ E. Other: *See Continuation Sheet*.
- ☐ 5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4):

_____

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714.

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted.
2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the correction, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action. If any of above boxes 1. to 4. are checked, the correction required is only the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121.

   Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

   Failure to timely respond to this notice will result in:
   Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or
   Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

Legal Instruments Examiner (LIE), if applicable _____ Telephone No. _____

Continuation of 4(e) Other: Claim 26 is amended and not indicated by the proper status identifier. Claims 29-34 are withdrawn claims and are not identified by the proper status identifier.